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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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Dilip K. Nakhasi

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COOK ALEX LTD

SUITE 2850

200 WEST ADAMS STREET

CHICAGO, IL 60606

EXAMINER

PADEN, CAROLYN A

ART UNIT

PAPER NUMBER

1781

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DELIVERY MODE

12/29/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/795,843             | NAKHASI ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Carolyn A. Paden       | 1781                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,8,9,11-13,15-17,22,23,37,40,41,43,44 and 46-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,11-13,15-17,22,23,37,40,41,43,44 and 46-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 22, 2010 has been entered.

Claims 1-5, 8, 9, 11-13, 15-17, 22, 23, 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 1 for "said domestic oil". An amendment to the claims clarifying this issue would overcome the rejection. It is unclear in claim 1 as to what is included in the medium chain vegetable triglyceride. Claim 1, line 11 calls for a medium chain triglyceride with at chain length of least C16. This does not agree with what is set forth in the specification in paragraph 0019. Applicant appears to have omitted some

lines from claim 1 when filling the present amendments to the claims.

Clarification is requested.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-9, 11-13, 15-17, 22-23, 37, 40-41, 43-44 and 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyama (6,827,963) in view of Wester (6,589,688) , CFR and St-Onge taken together as further evidenced by Baileys and Pelloso (5,434,278).

Aoyama discloses fats and oils for reducing lipids in the blood. The patent discloses the preparation of triglycerides from tricaprylin and oleic acid in the case of example 1; sunflower oil and caprylic acid in example 2 and triolein and caprylic in example 3. The synthesized triglycerides were treated to remove free fatty acids to provide triglyceride compositions shown in tables 1 and 4. The examples all use interesterification to prepare the triglycerides and at column 8, lines 18-23 the use of random or chemical interesterification is suggested. The synthesized triglycerides were used in test diets to show the healthful benefits of reduction of lipids in

the blood. The claims appear to differ from Aoyama in the recitation of way the triglycerides are made in claim 1. Aoyama utilizes a combination of a fatty acid and a triglyceride to provide a triglyceride containing medium chain fatty acids. Appellant utilizes two triglycerides in a randomization reaction. The final product in both the claims and Aoyama is a triglyceride containing both medium chain fatty acids and long chain fatty acids.

Aoyama describes his product as containing any of the possible combinations of medium and long chain fatty acids that can form a triglyceride, as shown in the formulas set forth on columns 2 and 3. The suggested triglycerides shown in Aoyama do not appear to favor one triglyceride over the other. Further, it would have been obvious to combine the triglycerides from the examples 1-3 to modify the triglyceride assortment in the diet. The claims also appear to differ from Aoyama in the inclusion of a phytosterol component. Wester is relied upon to show that incorporation of phytosterol esters in foods acts to lower the cholesterol of the body (column 1, lines 13-37). The concept of using phytosterol in cooking oils is specifically outlined in Wester at column 5, lines 35-37. CFR is relied upon to show the levels of phytosterol ester fortification required to make labeling claims with regard to lowering cholesterol and reducing the

risk of coronary heart disease at page 147(G)(1) & (2). Finally St-Onge teaches that oils rich in phytosterols and medium chain triglyceride oil are known in the art to improve plasma lipid profiles in man. With the references of Wester, CFR and St-Onge before him, it would have been obvious to one of ordinary skill in the art to fortify the oil of Aoyama with phytosterol esters to enhance the health benefits of the oil. The smoke point is not mentioned but Baileys provides evidence that the smoke point of vegetable oil is around 450F. The smoke point is said to decrease with increasing free fatty acid content and Baileys at pages 211-212 is cited for support of this assertion. Aoyama treats his oils to reduce the free fatty acid content of his triglyceride. One of ordinary skill in the art would expect the smoke point of Aoyama to fall within the range of the claims. Finally Baileys is relied upon in Table 3.11 at pages 194-195 to show the melting point of oleic acid and C8-C10 separately in triglyceride form. Both triolein and tricaprylin have a melting point of within the range of the claims. One of ordinary skill in the art would expect the interesterified mixture of fats in Aoyama to also have this melting point. It is appreciated that the storage stability and taste of the oil is not mentioned but one of ordinary skill in the art would have expected the triglyceride of Aoyama to have good storage

stability and taste because of the saturated fatty acid content of the triglyceride. One would not expect the oil of Aoyama to readily oxidize. To administer one particular amount of oil or the other would have been an obvious way to modify the caloric content of the diet.

The claims indicate that the fat portion of the composition is prepared by a randomization reaction. Applicant defines randomization at page 4, paragraph 7 with cited patents to describe chemical interesterification of fatty acid moieties to create a triglyceride. Aoyama contemplates this mode of interesterification at column 8, lines 19-23.

Applicant argues that he is performing a randomization reaction and thus cannot provide specific formulas for what triglycerides would form from his reaction. This has been considered but does not overcome the rejection. Aoyama shows all of the structural formulas possible from the random interesterification reaction of medium and long chain fatty acid sources with a source of glycerol.

Applicant argues Aoyama's only reference to using chemical synthesis is at column 8, lines 20-21 and that Aoyama has not provided an enabling disclosure for using chemical synthesis. This has been considered but is not persuasive. Chemical synthesis for randomization

reactions and interesterification is very well known in the art. Even Appellant admits that chemical randomization is known at page 4, paragraph 7 of his specification. The specification defines randomization at page 4, paragraph 7 with four cited patents to describe chemical interesterification of fatty acid moieties to create a triglyceride.

Applicant continues to argue that Aoyama is not enabling for a chemical synthesis method because he did not incorporate applicants' references into his specification. If further guidance were needed for chemical synthesis of the triglycerides of Aoyama, one of ordinary skill in the art would only need to look to Pelloso, who uses sodium alkoxide as the interesterification catalyst for interesterification (column 6, line 57).

Applicant argues that the cited patents do not enable randomization interesterification of the specific triglycerides of his claims. This has been considered but is not persuasive. In example 1, Pelloso interesterifies canola oil with triacetin and in example 5, Pelloso interesterifies triacetin, tributyrin, medium chain triglycerides and hydrogenated soybean oil. Both medium chain triglycerides and domestic oil are interesterified in Pelloso.



Applicant argues that one would need more details to perform random chemical interesterification in Aoyama. Pelloso is cited, if necessary to show these details.

Applicant argues that the secondary references to Wester, CFR, St-Onge and Bailey are not concerned with interesterification. Applicant urges that one would need more guidance on how to use the chemical synthesis but Pelloso is cited to provide these details.

#### CLAIM 15

Applicant argues that the references do not show a clear liquid that remains clear for six months. It is appreciated that Aoyama does not show the clear liquid structured lipid that is clear for six months. Baileys is relied upon in Table 3.11 at pages 194-195 to show the melting point of oleic acid and C8-C10 separately in triglyceride form. This data suggest that these fatty acids are liquid at room temperature. One of ordinary skill in the art would expect the structured lipid to be clear for six months because the structure lipid triglyceride is derived from fatty acids that are liquid.

#### CLAIM 16

Applicant argues that the composition has sensory qualities that are similar if not better than oil that does not have phytosterol in it. It is appreciated that the taste of the oil of Aoyama is not mentioned but one of ordinary skill in the art would not expect the oil of Aoyama to have a different taste when phytosterol is included. The phytosterol containing oil has the added health improving values as urged by CFR, Wester and St-Onge.

#### CLAIM 17

Applicant argues that the composition has sensory qualities that are similar if not better than oil that does not have phytosterol in it. It is appreciated that the taste of the oil of Aoyama is not mentioned but one of ordinary skill in the art would not expect the oil of Aoyama to have a different taste when phytosterol is included. The phytosterol containing oil has the added health improving values as urged by CFR, Wester and St-Onge.

#### CLAIM 37

Applicant argues that claim 37 is directed to a process and so the randomizing reaction is essential to the claim. Applicant argues that he is performing a randomization reaction and thus cannot provide specific

formulas for what triglycerides would form from his reaction. This has been considered but does not overcome the rejection. Aoyama merely shows the structural formulas possible from the triglyceride forming reaction of the combination of the first and second fatty acids. Examiner does not believe that the structural formulas of Aoyama and the claims are different.

Applicant argues Aoyama's only reference to using chemical synthesis is at column 8, lines 20-21 and that Aoyama has not provided an enabling disclosure for using chemical synthesis. This has been considered but is not persuasive. Chemical synthesis for randomization reactions and interesterification is very well known in the art. Appellant admits that chemical randomization is known at page 4, paragraph 7. The specification defines randomization at page 4, paragraph 7 with four cited patents to describe chemical interesterification of fatty acid moieties to create a triglyceride. If further guidance were needed for chemical synthesis of the triglycerides of Aoyama, one of ordinary skill in the art would only need to look to Pelloso, who uses sodium alkoxide as the interesterification catalyst for interesterification (column 6, line 57). Applicant argues that the cited patents do not enable randomization interesterification of the specific triglycerides of his claims. This has been

considered but is not persuasive. In example 1, Pelloso interesterifies canola oil with triacetin and in example 5, Pelloso interesterifies triacetin, tributyrin, medium chain triglycerides and hydrogenated soybean oil. Both medium chain triglycerides and domestic oil are interesterified in Pelloso.

Applicant argues that the secondary references to Wester, CFR, St-Onge and Bailey are not concerned with interesterification. These references are not relied upon to show chemical interesterification.

Applicant argues that Aoyama does not disclose Appellants' liquid lipid component. This is disagreed with. Claim 37 is a randomized interesterified product between a medium chain fatty acid source and a long chain fatty acid source. One of ordinary skill in the art would expect the triglycerides of Table 1 of Aoyama to result from this reaction. Varieties are formed with random placement medium or long chain fatty acids on the glycerol molecule.

Applicant argues that chemical synthesis is not the same thing as random interesterification. Applicant defines interesterification as a randomizing reaction in paragraph 7 of his specification. The fact that Aoyama does not select this method to make his product is not seen to

overcome the rejection because Aoyama provides for alternative way to prepare the triglyceride.

CLAIM 40 and Dependent claims 41, 43, 44 and 46

Applicant argues that he achieves better results than St Onge did in his clinical study. This as been considered but does not overcome the rejection. Aoyama and St-Onge both disclose that medium chain triglycerides are useful in improving health and nutrition. The LDL cholesterol of people consuming medium chain triglycerides was reduced in both Aoyama and St-Onge. One of ordinary skill in the art would expect the LDL cholesterol of people consuming Applicants' fat to also be reduced because it contains medium chain fatty acids.

CLAIM 47

Applicant argues that the references do not show a clear liquid that remains clear for six months. It is appreciated that Aoyama does not show the clear liquid structured lipid that is clear for six months. Baileys is relied upon in Table 3.11 at pages 194-195 to show the melting point of oleic acid and C8-C10 separately in triglyceride form. This data suggest that these fatty acids are liquid at room temperature. One of ordinary skill in the art

would expect the structured lipid to be clear for six months because the structure lipid triglyceride is derived from fatty acids that are liquid.

#### CLAIM 48

Applicant argues that the composition has sensory qualities that are similar if not better than oil that does not have phytosterol in it. It is appreciated that the taste of the oil of Aoyama is not mentioned but one of ordinary skill in the art would not expect the oil of Aoyama to have a different taste when phytosterol is included. The phytosterol containing oil has the added health improving values as urged by CFR, Wester and St-Onge.

Applicant urges that his product is even better than the medium chain triglyceride used in St-Onge. This has been considered but is not persuasive that the claims are unobvious over the references. The claims merely call for an improvement in LDL cholesterol reduction. The subjects tested in St-Onge were different from the subjects tested in Rudkowska in that the Rudkowska subjects were hyperlipidemic at the start of the testing. One would expect more improvement in the hyperlipidemic subjects because of the bigger change in diet that occurred as a result of

the test. The Rudkowska test was not designed to compare Aoyama in view of Wester, CFR, St-Onge and Baileys with Appellants' randomly interesterified structured lipid composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn A Paden whose telephone number is (571) 272-1403. The examiner can normally be reached on Monday to Friday from 7 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached by dialing 571-272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Carolyn Paden/

Primary Examiner 1781